The information contained in this guide is provided to assist you in understanding the reimbursement process. It is intended to assist providers in accurately obtaining reimbursement for health care services. It is not intended to increase or maximize reimbursement by any payor. We strongly suggest that you consult your payor organization with regard to local reimbursement policies. The information contained in this document is provided for information purposes only and represents no statement, promise or guarantee by Acclarent concerning levels of reimbursement, payment or charge. Similarly, all CPT® and HCPCS codes are supplied for information purposes only and represent no statement, promise or guarantee by Acclarent that these codes will be appropriate or that reimbursement will be made.

Please contact the Acclarent Reimbursement Hotline at 877.340.6466 if you need assistance.
INDICATIONS FOR USE

Q. What are the indications for use for the Acclarent AERATM Eustachian Tube Balloon Dilation System?

A. The ACCLARENT AERA™ Eustachian Tube Balloon Dilation System is intended to dilate the Eustachian tube for treatment of persistent Eustachian tube dysfunction in adults ages 22 and older.

COVERAGE

Q. Do payors cover Eustachian tube balloon dilation (ETBD) procedures?

A. Commercial Payors: Coverage policies may differ from plan to plan. For coverage details, contact the patient’s insurance plan directly.

Medicare: At this time, Medicare does not have a National Coverage Determination for ETBD procedures. Medicare allows coverage and payment for services considered medically necessary and reasonable. Coverage for ETBD is subject to standard medical necessity guidelines, which should be supported in patient medical records. However, some Medicare Administrative Contractors (MACs) may have special coverage requirements since the procedure is reported by an unlisted code. Please refer to your individual MACs coverage policies for more information.

Medicare Advantage Plans will most likely require prior-authorization of the ETBD procedure. Please consult the commercial plan directly for additional information.

PRIOR APPROVAL / AUTHORIZATION

Q. Do payors require prior-authorization for ETBD procedures?

A. Commercial: Coverage for ETBD procedures depends upon the insurance company. Prior to scheduling the procedure, the provider should contact the patient’s health plan to inquire if a prior-authorization is required for ETBD procedures. A Letter of Medical Necessity (LOMN) may be submitted to the payor detailing the ETBD procedure and medical necessity for the patient.

Medicare: Medicare does not provide prior authorization, prior approval or predetermination of benefits for any services. General coverage guidelines for many services can be found using the Medicare Coverage Database. The database is maintained by CMS and is located on their web site at http://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx. In the absence of a local or national coverage determination, the local MAC or carrier will determine whether coverage is available for a service on a case-by-case basis.

HMO/Medicare Advantage programs will most likely require prior-authorization of the ETBD procedure.

Q. What if my prior-authorization request is denied?

A. Prior-authorization may be denied because the payor could not determine the medical necessity and appropriateness of the proposed treatment, or the services are deemed experimental/investigational. Most payors will have their own appeals process and guidelines and will vary in their timelines and number of appeals that may be requested.
CODING

Q. What code should physicians use to report the ETBD procedure?

A. At the present time, a procedure-specific CPT® code does not exist for ETBD. The procedure should be reported by an available unlisted CPT® code.

69799 Unlisted procedure of the middle ear

Q. What code should facilities use to report the ETBD procedure?

A. When facilities are billing Medicare for services, C9745 may be used to report the procedure. When billing private and commercial payors the unlisted CPT® code should be utilized.

C9745 Nasal endoscopy, surgical; balloon dilation of eustachian tube

69799 Unlisted procedure of the middle ear

C1726 and C1769 describe the Acclarent AERATM Eustachian Tube Balloon Dilation System and should also be reported.

Q. What is a C-Code?

A. Level II HCPCS is a standardized coding system used primarily to identify products, supplies, and services not included in the CPT® Code Set. HCPCS C codes are reported for device categories, novel technology procedures, drugs, biologicals and radiopharmaceuticals that do not have other HCPCS code assignments. Key points regarding C codes include the following:

• Applicable for Hospital and ASC use. Physicians will continue to report the unlisted code.
• Are unique temporary pricing codes established by CMS for the Outpatient Prospective Payment System (OPPS).
• May be reported by facilities to Medicare and other payors utilizing the OPPS payment methodology. Facilities may continue to report the unlisted code with all other payors.
• Are not the same as Category III CPT® codes.

Q. When will a Category I CPT® code be implemented for this procedure?

A. Prior to the implementation of a Category I CPT® code, the American Medical Association has requirements that must be satisfied. The earliest a Category I code might be available for utilization is January 2019.

Q. Is there a global period associated with C9745?

A. There is no global period associated with C9745.

Q. Can I report ETBD with concomitant procedures?

A. There are no defined National Correct Coding Initiative (NCCI) edits that prohibit the billing of the unlisted CPT® code 69799 or C9745 with other procedures. Report the appropriate CPT® code(s) for other procedures performed during the same operative session as ETBD.

Please contact the Acclarent Reimbursement Hotline at 877.340.6466 if you need assistance.
EXAMPLES OF COMMONLY USED CPT® / HCPCS MODIFIERS

<table>
<thead>
<tr>
<th>MODIFIER</th>
<th>TYPE</th>
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<tbody>
<tr>
<td>50</td>
<td>Bilateral Procedure: When bilateral procedures are performed in the same session, append the additional procedure. 50% payment reduction of the second procedure generally applies.</td>
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<tr>
<td>51</td>
<td>Multiple Procedures: When multiple procedures, other than E/M Services are performed at the same session by the same provider, append the additional procedure or service code(s). Use of 51 is not required by all payors.</td>
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<tr>
<td>53</td>
<td>Discontinued Procedure: Under certain circumstances, the physician may elect to terminate the procedure.</td>
</tr>
<tr>
<td>73</td>
<td>Discontinued Outpatient Hospital/Ambulatory Surgery (ASC) Procedure PRIOR TO the Administration of Anesthesia – Applies when extenuating circumstances require the cancellation of a procedure.</td>
</tr>
<tr>
<td>74</td>
<td>Discontinued Outpatient Hospital/Ambulatory Surgery (ASC) Procedure AFTER Administration of Anesthesia – Applies when extenuating circumstances require the cancellation of a procedure.</td>
</tr>
<tr>
<td>RT</td>
<td>Right Side: Used to identify procedures performed on the right side of the body.</td>
</tr>
<tr>
<td>LT</td>
<td>Left Side: Used to identify procedures performed on the left side of the body.</td>
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Q. Do multiple procedure reduction rules apply to the unlisted code?

A. Yes, the multiple procedure reduction rule applies to the unlisted surgery code 69799. Medicare requires the use of modifier 51 to report multiple procedures. Commercial guidelines vary.

Q. How do I report bilateral procedures?

A. It is not appropriate to append modifiers to unlisted CPT® codes because the unlisted procedure codes in the CPT® codebook do not describe specific procedures. Instead, when reporting an unlisted code to describe a procedure or service, supporting documentation (eg, procedure report) should be submitted to provide an adequate description of the nature, extent, need for the procedure, time, effort, and equipment necessary to provide the service. If C9745 is used, a bilateral procedure may be reported using the modifiers RT or LT. Consult directly with the payor for specific guidelines.
PAYMENT

Q. Since the unlisted code does not have an established payment value, how will the ETBD procedure be paid?

A. Payment for procedures reported with an unlisted code is at the discretion of the payor. Providers should submit supporting documentation to the payor to accurately describe the work and resources associated with the procedure. The operative report is a key source of information and should include information such as the following:

- Level of difficulty of the case
- Patient’s diagnosis and duration of medical condition
- Risk of complication associated with the procedure
- Resources required to perform the procedure
- Anything unusual found during the procedure
- Other problems the patient is having and associated follow up care

Additionally, include a cover letter, which explains no specific CPT® code is currently available for this procedure and, therefore, the unlisted code was used. An established procedure code can be referenced, which is comparable in time, skill, and work to the ETBD procedure. Submit the claim with a brief explanation, including why the comparator CPT® code is similar to ETBD.

Be advised payors have their own guidelines for reviewing/adjudicating claims with unlisted codes. Check with your payor to inquire about individual requirements.

Q. What is the payment rate associated with C9745?

A. C9745 maps to APC 5165 with a status indicator of J1 and an ASC payment indicator of J8. Please consult the Eustachian Tube Balloon Dilatation Facility and Physician Reimbursement Guide for Medicare national average payments.

Q. Does C9745 align to a Comprehensive Ambulatory Payment Classification (C-APC)?

A. Yes, APC 5165 has a status indicator of J1, which means services are paid through a comprehensive APC. There is only one payment made to the hospital regardless of how many procedures are performed.

Please contact the Acclarent Reimbursement Hotline at 877.340.6466 if you need assistance.
APPEALS

Q. My claim has been denied. How can I move forward with obtaining reimbursement?

A. If a claim or service is denied, an appeal may be filed with the insurance company. The reason for the denial can be found in the denial letter and/or the explanation of benefits (EOB).

An appeal letter should be tailored to the reason for the denial and may include a corrected claim, product information, patient medical information, clinical data, and/or economic data, along with other supporting documentation.

Submitting relevant medical documentation, which may support the medical necessity of the service(s) provided, is critical to the appeals process. The documents listed below are examples of the types of information, which may be submitted in order to support the claim for payment of the service:

- Patient medical records
- Treatment plan
- Physician’s order
- Test results
- X-ray or CT Scan reports
- Operative report (detailed below)
- Product information
- Specific reasons why the physician believes the ETBD procedure is medically necessary
- Relevant clinical data
- List of failed conservative or alternative treatments
- Discharge notes

CODING RESOURCES AND REFERENCES

The following are some of the coding resources available to assist in accurately reporting ETBD services, procedures, and devices.

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<td>- CPT® Network: An online, subscription-based service for coding information: <a href="http://www.cptnetwork.com">www.cptnetwork.com</a></td>
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<tr>
<td>For additional information please contact the Acclarent Reimbursement Hotline:</td>
<td>- CPT® Assistant: A monthly coding publication of the American Medical Association</td>
</tr>
<tr>
<td>877.340.6466 or email us at <a href="mailto:acclarent.reimbursement@milestonecro.com">acclarent.reimbursement@milestonecro.com</a></td>
<td>- ICD-10-CM 2017 Standard, Complete Official Codebook. AMA ©2016 (<a href="http://www.nchs.cdc.gov">www.nchs.cdc.gov</a>) and is available from multiple publishers</td>
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<tr>
<td></td>
<td>Medicare Program website: <a href="http://www.cms.gov">www.cms.gov</a></td>
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<tr>
<td></td>
<td>- Provides a wide range of information and resources</td>
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<table>
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<tr>
<th>OTHER RESOURCES:</th>
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FOR ADDITIONAL QUESTIONS OR INFORMATION CONTACT:
Acclarent.reimbursement@milestonecro.com
877.340.6466

Please contact the Acclarent Reimbursement Hotline at 877.340.6466 if you need assistance.
Caution: Federal (U.S.) law restricts the sale, distribution or use of the ACCLARENT AERA™ by or on the order of a physician who is trained in the use of Acclarent technology. Eustachian tube balloon dilation has associated risks, including tissue and mucosal trauma, infection, or possible carotid artery injury. Prior to use, it is important to read the Instructions for Use and to understand the contraindications, warnings, and precautions associated with these devices.

For Physicians: ACCLARENT AERA™ is intended for use by physicians who are trained on Acclarent technology. Eustachian tube balloon dilation has associated risks, including tissue and mucosal trauma, infection, or possible carotid artery injury. Prior to use, it is important to read the Instructions for Use and to understand the contraindications, warnings, and precautions associated with these devices.